

REMARKS

Status of the Claims

Claims 24-25, and 28-35 are amended and new claims 36-45 are added to correct improper multiple dependencies. No new matter has been added. Upon entry of this Amendment, claims 1, 6-7, 9-10, 14, 16-17, and 19-45 are pending, and elected claims 24-45 should be examined. Applicants will request rejoinder when the elected claims are allowed.

Information Disclosure Statement

The IDS filed has been unconsidered but placed in the file on the grounds that the reference by Maruyama et al. is in a foreign language and therefore fails to comply with the provisions of 37 CFR 1.97, 1.98, and MPEP § 609. See Office Action mailed April 7, 2003, page 2. Applicants submitted Maruyama et al. with the paper titled "Concise Explanation of Japanese Reference" affixed. Applicants respectfully request reconsideration and an indication that Maruyama et al. was considered by returning the Form PTO 1449 filed December 26, 2001, with the Examiner's initials.

Objections to the Specification

The specification has been objected to because it contains an embedded hyperlink and browser-executable code. See Office Action, page 2. Applicants have amended the specification and respectfully request reconsideration and withdrawal of the objection.

Rejections- 35 U.S.C. § 101

Claims 24-35 are rejected under 35 U.S.C. §101 for alleged lack of a well-established utility. Applicants respectfully traverse this rejection.

According to the PTO, the claimed invention lacks a specific, substantial, and credible utility, or alternatively, a well-established utility. Office Action, p. 3. For this type of rejection, because utilities are asserted in the application, the rejection must be supported by explanation and supporting evidence. MPEP § 2107. Otherwise a rejection is improper and should be withdrawn.

Such is the case here. For example, the specification teaches that SEQ ID NO 706 and SEQ ID NO 6223 of the elected claims have a specific utility, i.e., a utility specific to SEQ ID NO 706 and SEQ ID NO 6223. Not only are SEQ ID NO 706 and SEQ ID NO 6223 described as making it possible to encode a membrane or secretory protein, but both SEQ ID NO 706 and SEQ ID NO 6223 are also described as associated with diabetes. Specifically, according to the specification, the expression level of HEMBA1004850, a clone containing SEQ ID NO 706 and SEQ ID NO 6223, was elevated in endothelial cells in a glycated protein specific manner (see p. 420, lines 30-42, and p. 632, line 9 of Table 169). As further disclosed in the specification on page 407, line 21, a non-enzymatic protein glycation reaction is believed to cause of a variety of chronic diabetic complications. Schmidt AM et al., *J Clin Invest.* Sep. 96(3):1395-403 (1995) (reporting a gene whose expression is significantly elevated or decreased in a glycated protein-specific manner in an endothelial cell and is associated with a diabetic complication caused by a glycated protein) (enclosed for consideration). HEMBA1004850 contains such a gene and both SEQ ID NO 706 and SEQ ID NO 6223. Therefore, both SEQ ID NO 706 and SEQ ID NO 6223 find a specific utility in the diagnosis and treatment of diabetes. For example, SEQ ID NO 706, SEQ ID NO 6223, and SEQ ID NO 10847 and SEQ ID NO 10848 can serve as targets for developing a therapeutic agent for combating protein glycation and the complications of diabetes resulting therefrom.

Furthermore, not only is this utility specific to SEQ ID NO 706, SEQ ID NO 6223, and SEQ ID NO 10847 and SEQ ID NO 10848, but this utility is also substantial, i.e., defines a real world use for reasons that should need no explanation. Cf. MPEP 2107.01 I. Nevertheless, SEQ ID NO 706, SEQ ID NO 6223, and SEQ ID NO 10847 and SEQ ID NO 10848 find substantial, real world utility in the screening assays described on page 180, line 34 through page 182, line 7.

Moreover, the evidence and explanation of record fail to address the credibility of these specific and substantial utilities. Therefore, the rejection is improper and should be withdrawn.

Rejections- 35 U.S.C. § 112, first paragraph (Enablement)

Claims 24-35 are rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement. In short, the PTO asserts that the claimed invention is not supported by a specific, substantial, and credible utility or a well-established utility, and therefore one skilled in the art would not know how to use the claimed invention. Applicants respectfully traverse this rejection.

A claim as filed is presumed to be enabled by a specification, and thus, in compliance with the enablement requirement of Section 112, first paragraph. The burden is on the Patent Office to establish a reasonable basis to question enablement. The test of enablement is whether one reasonably skilled in the art could make and use the claimed invention from the disclosures in the patent coupled with information known in the art without undue experimentation. Regarding the “how to use” prong, it is important to note that Section 112, first paragraph, does not require a specification to enable all uses of the claimed invention. Rather, a single disclosed or well-established use commensurate in scope with the claims is all that is required.

As previously discussed, the subject matter embraced by the elected claims and sequences find specific, substantial, and credible utility. This issue has been addressed in the previous section and need not be repeated here. In light of the disclosed utility, however, Applicants respectfully submit that one skilled in the art, guided by the present specification’s teachings, would readily know how to make and use the claimed invention. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

Rejections- 35 U.S.C. § 112, first paragraph (written description)

Claims 24-35 are rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of written description. As there are numerous written description rejections, each is addressed and enumerated as in the Office Action, pages 8-9.

1. Claims 24 and 27-35 have been rejected for reciting that article “the.” Office Action, page 8. The present version of the claims avoids this issue. The Examiner is thanked for her astute observation.

2. Claim 28 has been rejected for reciting “70% identical.” The present version of the claim avoids this issue. Thus, the rejection should be withdrawn.

3. Claim 28 has been rejected for reciting “functionally equivalent.” The present version of the claims avoids this issue. Thus, the rejection should be withdrawn.

4. Claim 28 has been rejected for reciting “partial.” The present version of the claims avoids this issue. Thus, the rejection should be withdrawn.

Accordingly, Applicants respectfully submit that the present version of the claims comply with the written description requirements of 35 U.S.C. § 112, first paragraph.

Rejections- 35 U.S.C. § 112, Second Paragraph

Claims 24-35 are rejected under 35 U.S.C. §112, second paragraph, for alleged indefiniteness. As there are numerous indefiniteness rejections, each is addressed and enumerated as in the Office Action, pages 10-11.

1. Claims 24, 25, and 34 have been rejected for reciting “complementary to.” Office Action, page 10. The present version of the claims avoids this issue. Thus, the rejection should be withdrawn.

2. Claims 24 and 26-35 have been rejected for reciting that article “the.” Office Action, page 10. The present version of the claims avoids this issue. Thus, the rejection should be withdrawn.

3. Claim 28 has been rejected for reciting “functionally equivalent.” Office Action, pages 10-11. The present version of the claims avoids this issue. Thus, the rejection should be withdrawn.

4. Claim 28 has been rejected for reciting “partial.” Office Action, page 11. The present version of the claims avoids this issue. Thus, the rejection should be withdrawn.

5. Claim 28 has been rejected for reciting “hybridizes.” Office Action, page 11. The present version of claim 28 recites hybridization conditions, which finds support in the specification, for example, at page 10. Thus, the present version of the claim avoids this issue, and the rejection should be withdrawn.

6. Claims 34-35 have been rejected for reciting “complementary strand thereof” and “portion thereof.” Office Action, page 11. The present version of the claims avoids this issue. Thus, the rejection should be withdrawn.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejections.

Rejections- 35 U.S.C. § 102(b)

Rejections in view of Trofatter et al.

Claims 24-27 and 34-35 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Trofatter et al. (USPN 5,707,863). Applicants respectfully traverse this rejection.

A reference anticipates a claim only if that reference describes each and every element of the claim. MPEP § 2131. If even just one element is absent from the reference’s particular disclosure, that disclosure neither describes nor anticipates the claim. *Id.* Such is the case in this rejection.

According to the PTO, Trofatter discloses a 20-mer primer that is 65% homologous to a section of the complement of the complementary strand of SEQ ID NO. 702. Trofatter further discloses a 22-mer primer which is 36% complementary to SEQ ID NO. 6223. Office Action, page 12.

Even if the PTO’s position were accurate, Trofatter would not describe “an oligonucleotide comprising an at least 15 nucleotide fragment of the nucleotide sequence set

forth in SEQ ID NO 702.” This means that Trofatter never describes “an oligonucleotide comprising an at least 15 nucleotide fragment of the nucleotide sequence set forth in SEQ ID NO 702.” Accordingly, Trofatter et al. does not anticipate claims 24-27 and 34-35.

Applicants respectfully request reconsideration and withdrawal of the rejections.

Rejections in view of Shin et al.

Claims 28-35 are rejected under 35 U.S.C. § 102(e)(1) as allegedly being anticipated by Shin et al. (USPN 6,291,645). According to the PTO, Shin et al. discloses a 22-mer which matches residues 767-788 of SEQ ID NO. 10847, thereby allegedly anticipating claims 28 *et seq.*

Even if the PTO were correct, the 22-mer would not describe SEQ ID NO. 10847, itself. Please assess the scope of the present claims. MPEP § 2111. If this rejection is maintained, please call Sean Passino (45,943) to clarify the basis. Accordingly, claims 28-35 are not anticipated by Shin et al.

CONCLUSION

As the above-presented amendments and remarks address and overcome all of the rejections presented by the Examiner, withdrawal of the rejections and allowance of the claims are respectfully requested. No new matter has been added.


If there are any questions concerning this application, the Examiner is courteously invited to contact the undersigned counsel.

Respectfully submitted,

Date

9/8/13

By

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Should additional fees be necessary in connection with the filing of this paper, or if a petition for extension of time is required for timely acceptance of same, the Commissioner is hereby authorized to charge Deposit Account No. 19-0741 for any such fees; and applicant(s) hereby petition for any needed extension of time.

Enclosure:

Schmidt AM et al., *J Clin Invest.* Sep. 96(3):1395-403 (1995)